West Virginia Pharmaceutical Cost Management Council Meeting Minutes March 4, 2005 at 11:30 a.m. State Capitol Complex, Building 1, Room 157K Charleston, West Virginia 25305

Members Present:Absent:Others Present:Shana Phares, ChairPhil ShimerSee Attached Register

Shana Phares, Chair Phil Shimer Robin Perdue Heather Bresch

Nancy Atkins Robert Ferguson, Co-Chair

Peggy King William Lytton Felice Joseph

Dr. Wayne Spiggle Kevin Outterson Laddie Burdette Stephen Neal

Attending the meeting as a representative for Heather Bresch of Mylan Laboratories was Leah L. Summers.

Ms. Phares called the meeting to order.

Cathy McDougall, Senior Legislative Representative from the AARP Department of State Affairs at the national office in Washington, D.C. gave a presentation on Prescription Drug Reimportation and Safety. She stated that AARP wishes to raise awareness on price cost of drugs, especially to the elderly and they applaud the Pharmaceutical Council for their work.

While the Medicare prescription drug benefit was an important first step in helping those over 65, more needs to be done to control the rising costs of prescription drugs so that Americans of all ages can afford needed medications. High drug prices combined with the surging older population are taking a toll on state budgets and private sector health insurance costs. Surveys conducted by AARP demonstrate that their members consider drug prices exorbitant and the single most significant barrier to obtaining needed medications.

Bill Novelli, CEO of AARP, announced that passing a federal law allowing people across the county to safely buy prescription drugs from Canada is one of AARP's top national priorities. AARP supports the Dorgan-Snowe prescription drug importation bill (S. 334) and its House companion, the Emerson-Brown bill (H.R. 700) which would legalize personal and wholesale importation of prescription drugs, starting with Canada, for three reasons: 1) it includes strong safety protections; 2) it attempts to prevent the drug industry from limiting supplies of drugs that would prevent importation; and 3) the Dorgan-Snowe and Emerson-Brown bills have bipartisan support.

AARP believes West Virginia could take a lead role and advocate to the federal government to allow for the safe reimportation of prescription drugs - as many state and localities are attempting to do across the country.

Philip A. Reale, Attorney and Government Relations Consultant, next introduced Peter Pitts, who is a Senior Fellow for healthcare studies at the Pacific Research Institute and Senior Vice President for Health Affairs at Manning, Selvage and Lee. From 2002-2004 Mr. Pitts was FDA's Associate Commissioner for External Relations, serving as the agency's "Chief Messaging Officer" where his challenge was to clearly define FDA's brand image and to communication the agency's main themes to its many constituencies.

Mr. Pitts stated that if you walk into a pharmacy in Windsor, Ontario and have your prescription filled by a real pharmacist - the drugs you receive will be both safe and effective. BUT - when the "learned intermediary" - a doctor or pharmacist - is replaced by a greedy intermediary (a storefront drug dealer or an unregulated internet site) then all bets are off.

Recently, the Canadian Health Minister, the Honorable Ujjal Dosanjh who, under tremendous political pressure to continue a charade, instead told the truth about the cross-border drug trade and the dangers that it poses to Americans and Canadians both. "I want to make sure that we don't have . . . 250 million Americans buying drugs in Canada. We cannot be the drugstore for the United States. The Minister clearly sees that as the Internet pharmacy cowboys soak up the Canadian drug supply for their own profit, domestic Canadian pharmacists are reporting more and more shortages.

Mr. Pitts cited several examples of Canadian pharmacies engaging in dangerous practices during pre-announced visits by Minnesota State officials. He stated that the FDA is faced with enough challenges policing drug safety at home; do we really want them to stretch their resources even further and become responsible for drug safety globally. According to the recent report issued under the signature of Admiral Richard Carmona, the Surgeon General of the United States, opening up our borders to drugs from Canada would result in an uncontrollable influx of untested, impure, expired, and counterfeit drugs from around the world.

Ms. Phares then introduced Scott Brown who was recently appointed by Governor Manchin to serve as West Virginia's Pharmaceutical Advocate. Welcome Scott!

After a short break, Ms. Phares then introduced Dr. Wayne Spiggle, who along with Robin Perdue is co-chairing the Central Fill Pharmacy Subcommittee. Council members were provided with a copy of the Subcommittee's Concept Paper entitled "Implementing West Virginia's Central Fill Pharmacy". Dr. Spiggle thanked those who served on this subcommittee for their help and hard work on this concept paper. He stated that this is not a structured business paper—it's a concept paper. We are now only serving about 1/3 of the patients in need, but this concept paper should help.

Ms. Phares asked for a motion to accept Dr. Spiggles' concept paper. A motion to accept the concept paper was made by Peggy King. Seconded by Kevin Outterson. Motion carried unanimously.

Next presenting to the Council was Brian Cunningham, Assistant Director, West Virginia Primary Care Association, who discussed Remote Delivery Around the Country. Mr. Cunningham discussed the need for remote delivery, the economic value of remote delivery and gave an overview of existing remote delivery models that included: automated remote delivery, prepackaged dispensary system, fill-and-delivery system, remote delivery of bulk replenishment patient assistance program drugs, similarities to the proposed system, existing infrastructure and demonstrated leadership. He also provided an overview of states (Texas, North Dakota and Minnesota) that permit remote delivery.

Dr. Spiggle offered the following: "that the Pharmaceutical Cost Management Council 1) approve the concept of remote delivery of medications under circumstances that will improve patient care, and 2) recommend to the Governor and the Legislature that relevant West Virginia Code be amended to allow a patient's "medical home," i.e. (clinical setting) to receive delivery of prescription medications and to allow community health centers to transfer pharmacist dispensed, retail prescriptions when a pharmacist is not physically present."

Two amendments to the motion were offered as follows: 1) The Council makes this recommendation with the understanding that the West Virginia Board of Pharmacy will promulgate legislative rules and policies to govern remote dispensing; and 2) Change the words "community health centers" to Federally Qualified Health Centers (FQHC).

A motion to approve the concept of remote delivery was made by Dr. Wayne Spiggle. Seconded by Kevin Outterson. Motion carried 8-1.

Next Ken Stone introduced Joanie Constante from Morgantown, Yvonne Jones from Huntington, Jeff Graham from Beckley and Pat White from West Virginia Health Right, who is also a member of the National Association of Free Clinics. Ms. White stated that the first free clinic was started 23 years ago and in West Virginia we now have 12. One of the goals of the free clinics is to break the habit of the under-insured using the hospital emergency room. She stated that all free clinics need volunteers to make them work. The free clinics mission is to provide healthcare to the needy and remember all the clinics are non-profit - we diagnose, treat and help educate. Hospitals support free clinics because it saves the hospital money. Free clinics provide services to the uninsured poor needing medical care, including diagnosis, laboratory, radiology tests and medications as well as dental care and treatment. They also provide prescription coverage to the under-insured. No free clinics dispense controlled drugs and all their patients get their medications on the same day. Mailing of medications is not timely for the patient.

In response to a question from Laddie Burdette as to "how will the central fill pharmacy compete?", Ms. White indicated that she doesn't think that is a problem - every free clinic is overloaded and any help this group (the Council) or the Legislature gives is greatly appreciated and a central fill pharmacy may help speed up care. They encourage all their patients to make appointments, but will take walk-ins. Everyone must have "proof of income" and all clinics do turn patients away, but we will tell them about a primary care center. No free clinic will

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dispense expired drugs—they do "red-bag" expired drugs, which means they are burned. Free clinics will donate to national groups when medication is useful to someone else.

Members of the Council were previously emailed copies of the Minutes of the Council Meeting held on January 27, 2005. Ms. Phares asked if anyone had questions or corrections. On page four, 4th paragraph, 340b Program, Ms. King needs to be changed to Ms. Atkins (Nancy). On page 2, paragraph 3, 3rd sentence states "Ms. Atkins stated nurse practitioners . . .This comment was made by Ms. Phares and not Ms. Atkins.

A motion to approve the minutes as amended was made by Laddie Burdette. Seconded by Dr. Wayne Spiggle. Motion carried unanimously.

The next regularly scheduled Council meeting will be held on April 11, 2005 and agenda items will include Health in Kentucky.

A motion to adjourn the meeting was made by Peggy King. Seconded by Felice Joseph.